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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,672	08/31/2001	Victor E. Vandell	P 0282906	7805

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EXAMINER

LAMM, MARINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding..

**Office Action Summary**

Application No.

09/942,672

Applicant(s)

VANDELL, VICTOR E.

Examiner

Marina Lamm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 4-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Acknowledgment is made of the amendment filed 2/24/06. Claims pending are 1, 2 and 4-25. Claim 3 has been cancelled. Claims 1, 18 and 20-23 have been amended.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackson et al. (US 6,461,644).

Jackson et al. teach anesthetizing polymer systems comprising a hydrophobic polymer (e.g. polyvinyl chloride, "PVC") and a topical anesthetic such as lidocaine base, prilocaine base and/or tetracaine. See Abstract; col. 15, lines 50-62; Examples. Jackson et al. teach that lidocaine base and prilocaine base form an oily liquid mixture. See col. 15, lines 50-55. The delivery systems of Jackson et al. may also include fatty alcohols such as lauryl alcohol or oleyl alcohol. See col. 15, line 49; col. 16, lines 33-37; col. 21, Example 9. The anesthetizing polymer systems of Jackson et al. may be used as transdermal patches for providing an anesthetizing effect for hair removal procedures such as laser, waxing or electrolysis. See col. 20, Example 6; col.

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31, lines 34-42. Jackson et al. teach applying lidocaine and polymer-containing transdermal patch (layer) to the site to be treated, leaving it on for a sufficient time to produce an anesthetizing effect, and then removing the patch (layer) from the skin. See col. 20, Example 6.

Thus, Jackson et al. teach each and every limitation of Claims 22-25.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 2, 4-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 4,052,513) in view of Smith (US 5,874,074), both of record.

Kaplan teaches topical oil-in-water emulsions containing, in an oil phase, 0.5-15% of benzocaine solubilized in ester solubilizers of the instant invention. See Abstract; col. 1, lines 45-60; Example I. These solubilizers are used in concentration of 5-40% and impart desirable emollient properties to the compositions. See col. 1, lines 30-44, 56-60. The compositions of Kaplan may contain polyethylene glycol, polyethylene glycol esters having MW of 200-600, thickeners such as xanthan gum, viscosity control agents such as paraffin and other cosmetic materials. See col. 2. The reference does not teach copolymers and plant oils of the instant claims. However, Smith teaches using PVP/hexadecane copolymer (Ganex V-216) as well as other PVP copolymers as barrier polymers "to form an occlusive or semi-occlusive film-like barrier

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on the surface of the skin to prevent evaporative loss of moisture from the skin, and protect the skin against environmental irritants" in topical formulations. See col. 4, lines 5-28. Further, the compositions of Smith may contain 0.05-1.5% of floral oils as fragrances "for cosmetic purposes." See col. 6, lines 35-48. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Kaplan such that to employ PVP copolymers such as PVP/hexadecane copolymer. One having ordinary skill in the art would have been motivated to do this to obtain an occlusive or semi-occlusive film-like barrier on the surface of the skin to prevent evaporative loss of moisture from the skin, and protect the skin against environmental irritants as suggested by Smith. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Kaplan such that to employ floral oils. One having ordinary skill in the art would have been motivated to do this to obtain fragranting effect as suggested by Smith.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US 6,461,644).

Jackson et al. applied as above. With respect to Claim 20, Jackson et al. does not explicitly teach applying the anesthetizing polymer patches (layers) to the scalp.

However, the anesthetizing method of Jackson et al. is suitable for removing hair from the skin by laser treatment, waxing or electrolysis, as discussed above. One skilled in the art would reasonable expect that the method of Jackson et al. is suitable for the

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hair removal from any part of the body, including scalp. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the anesthetizing method of Jackson et al. such that to use it for hair removal from the scalp. One having ordinary skill in the art would have been motivated to do this because the method produces a sufficient block to withstand the treatment without pain, as suggested by Jackson et al. (see Examples).

### ***Response to Arguments***

6. Applicant's arguments with respect to Claims 20 and 22-25 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

The previous rejections of Claims 20 and 22-25 have been withdrawn in view of the Applicant's amendment of Claims 20 and 22.

7. Applicant's arguments with respect to Claims 1, 2, 4-19 and 21 have been fully considered but they are not persuasive.

The Applicant argues:

"Thus, Kaplan and Smith both teach composition that they each independently classify as oil-in-water emulsions. As known to those of skill in the art, oil-in-water emulsions consist of a continuous phase (water) and a disperse phase (oil), and typically have the consistency of milk or lotion. In contrast to the teachings of Kaplan and Smith, Applicants have amended claims 1 and 21 to recite oil-based formulations. Oil-based formulations are different from an oil-in-water emulsion in that no emulsion is formed and water is not used as a continuous phase. Because Kaplan and Smith fail to teach or suggest oil-based formulations, the references, alone or in combination, fail to render obvious Applicants claimed invention." See p. 7 of the reply.

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In response, the instant specification defines "oil-based formulation" as those containing "both a therapeutically effective amount of a solubilized topical anesthetic and scalp/skin conditioning oils." See [0009]. Further, instant Claim 19 recites that the formulation "is a lotion". The formulations of Kaplan can be considered "oil-based" because they contain oily substances such as ester solubilizers (col. 1, lines 46-60), cetyl alcohol, lanolin (col. 2, line 24) and paraffin (col. 2, line 28). Further, it is noted that the features upon which applicant relies (i.e., the claimed formulation is not an emulsion and water is not used as a continuous phase) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,993,836; US 5,853,709.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at (571) 272-0646.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm, M.S., J.D.  
Patent Examiner  
Technology Center 1600

A handwritten signature in black ink, appearing to read "Johann R. Richter", with a large, stylized loop at the end.

Johann R. Richter, Ph.D., Esq.  
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